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10/700,171

11/03/2003

David L. Hallahan

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06/13/2006

E I DU PONT DE NEMOURS AND COMPANY  
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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/700,171

Applicant(s)

HALLAHAN ET AL.

Examiner

Richard G. Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Applicants amendment of claims 1, 2, 8, and 11 and the cancellation of claims 3, 4, and 13-15 in the paper of 11/3/2003, is acknowledged. Claims 1, 2, 5-12 are still at issue and are present for examination.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosure statement, filed on 11/3/2003, is acknowledged. Those references considered have been initialed. Those references not initialed are not considered complete. Applicants attention is directed to the directions for the information which should be provided for each reference to be considered.

### ***Claim Objections***

Claims 1, 2, 5-12 are objected to because of the following informalities:

Claim 1 (2, and 5-12 dependent on) is drawn to an isolated nucleic acid that "hybridizes with a nucleic acid sequence of (a) when washed with: 0.1XSSC, 0.1%SDS, 65°C". The reference to those nucleic acids that "hybridize when washed" is objected to

as being unclear. Such molecules that “hybridize when washed” are not supported by applicant’s specification, and it is believed that applicants should refer to both hybridization conditions followed by wash conditions.

Claim 5 recites “...the isolated nucleic acid fragments of Claim 1...” Claim 1 is drawn to an isolated nucleic acid fragment. It is realized that many nucleic acid fragments are encompassed by the nucleic acid fragment of claim 1, but the reference in claim 5 to nucleic acid fragments (plural) is confusing in that it appears that applicant is attempting to claim a chimeric gene that comprises multiple fragments. It is suggested that the recitation in claim 5, “...the isolated nucleic acid fragments of Claim 1...” be amended to recite “...the isolated nucleic acid fragment of Claim 1...”

Claim 9 is missing a “period” at the end of the claim.

Appropriate correction is required.

### ***Specification***

The disclosure is objected to because of the following informalities:

It is noted that in applicants transmittal sheet, applicants have indicated that the instant application is a divisional of 09/655,908. Such a characterization of the instant application is objected to on the basis that claim 1 is drawn to an isolated nucleic acid that “hybridizes with a nucleic acid sequence of (a) when washed with: 0.1XSSC, 0.1%SDS, 65°C” and the application 09/655,908 which applicants claim this application is a divisional of does not support such hybridization conditions. Thus the instant application is a continuation-in-part of this parent, not a divisional.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 5-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (2, 5-12 dependent on) is indefinite and confusing in that it is drawn to an isolated nucleic acid fragment encoding a plant *cis*-prenyltransferase protein selected from the group consisting of: parts (a); (b) or (c); Part (c) is drawn to an isolated nucleic acid fragment that is completely complementary to (a) or (b), (c). Inclusion of group (c) an isolated nucleic acid fragment that is complementary to (a), (b), (c), (d), (e) or (f), within this group is improper since a limitation of the claim is that the isolated nucleic acid fragment must encode a plant *cis*-prenyltransferase protein and the complement of a nucleic acid that encodes a plant *cis*-prenyltransferase protein, by definition would not also encode a plant *cis*-prenyltransferase protein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those isolated plant host cells transformed with a nucleic acid fragment encoding a *cis*-prenyltransferase protein consisting of the amino acid sequence of SEQ ID NO: 4, does not reasonably provide enablement for any transformed host cells transformed with a nucleic acid fragment encoding a *cis*-prenyltransferase protein consisting of the amino acid sequence of SEQ ID NO: 4, wherein said host cell is encompassed within a transgenic plant. Further applicants specification is not enabled for those methods of altering the level of expression of a plant *cis*-prenyltransferase protein involving antisense molecules or those methods wherein said alteration results in a modulation in the defense mechanism of the plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 6-12 are so broad as to encompass any transformed host cell transformed with a nucleic acid fragment encoding a *cis*-prenyltransferase protein consisting of the amino acid sequence of SEQ ID NO: 4, wherein said host cell is encompassed within a transgenic plant or any method of altering the level of expression of a plant *cis*-prenyltransferase protein involving antisense molecules of SEQ ID NO: 4 or those methods wherein said alteration results in a modulation in the defense mechanism of the plant.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the generation of those transgenic plants comprising a host cell comprising a nucleic acid that encodes a *cis*-prenyltransferase and hybridizes to that nucleic acid that encodes SEQ ID NO: 4. The transfer of foreign genes to cells of many plants and the subsequent generation of a transgenic plant, is not enabled given technologies available at the time of filing. Applicants disclose limited examples of such host cells within a transgenic plant, such that applicants have not enabled the vast scope of those plants encompassed by the claims. Further, applicants have not enabled those methods of antisense technology or those methods of modulation in the defense mechanism of a plant.

While recombinant and mutagenesis techniques are known, it is not routine in the art to practice the methods and generate the transgenic plants, as encompassed by the instant claims.

The specification does not support the broad scope of the claims which encompass transgenic plants and antisense methodologies, because the specification

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does not establish: (A) methods of performing and generating such; (B) the general tolerance of a host cell to modulations in plant *cis*-prenyltransferase and the result of such modification and extent of such tolerance; (C) a rational and predictable scheme for generating a plant host cell comprising a plant *cis*-prenyltransferase protein with an expectation of obtaining the desired biological function and its effect; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to generate the encompassed transgenic plants claimed and the fact that such generation are not well understood and are not predictable (e.g., see Potrykus, Ingo, Biotechnology Vol 8 (6), pp 535-542, June 1990, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those host cells and methods of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any transformed host cell transformed with a nucleic acid fragment encoding a *cis*-prenyltransferase protein consisting of the amino acid sequence of SEQ ID NO: 4, wherein said host cell is encompassed within a transgenic plant. Further applicants specification is not enabled for those methods of altering the level of expression of a plant *cis*-prenyltransferase protein involving antisense molecules or those methods wherein said alteration results in a modulation in the defense mechanism of the plant.. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)).



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Without sufficient guidance, generation of the encompassed plants and determination of those methods having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

***Remarks***

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'R. G. Hutson', followed by a horizontal line extending to the right.

Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit 1652

rg  
6/7/2006